

17. (Amended) The [Tracheal] cannula based on claim 5, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

18. (Amended) The [Tracheal] cannula based on claim 6, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

B1 19. (Amended) The [Tracheal] cannula based on claim 7, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

20. (Amended) The [Tracheal] cannula based on claim 13, wherein said balloon means comprises a pilot balloon.

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**REMARKS**

Claims 1- 20 have been amended. Upon entry of the amendment, claim 20 will be pending in the application. Reconsideration of the various objections and rejections set forth in the Office Action dated April 4, 2003 is respectfully requested in view of the foregoing Amendment and following Remarks.

**Claim Objections**

Claims 2-20 have been objected to on the basis that the "[u]se of the article "The" at the beginning of each claim is more grammatically accurate". The Applicant has amended claims 2-20 in a manner consistent with the Examiner's comment.

**Claim Rejections 35 U.S.C. §112 Second Paragraph**

Claims 1-20 have been rejected under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention".

Claim 1 has been specifically rejected as "failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention". The Examiner has asserted that "[t]here is insufficient antecedent basis for" the limitation "the tracheal cross sectional area" in lines 2-3. Claim 1 has been amended. As amended, claim 1 particularly points out and distinctly claim the subject matter which Applicant regards as the invention, and obviates the indefinite grounds rejection of 35 U.S.C. §112, second paragraph.

Claim 1 has been specifically rejected as "failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention". The Examiner has asserted that "[t]here is insufficient antecedent basis for" the limitation "the section of the shaft above the cuff" in lines 3-4. Claim 1 has been amended. As amended, claim 1 particularly points out and distinctly claim the subject matter which Applicant regards as the invention, and obviates the indefinite grounds rejection of 35 U.S.C. §112, second paragraph.

Claim 1 has been specifically rejected as "failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention". The Examiner has asserted that "[t]here is insufficient antecedent basis for" the limitation

"This" in line 5. Claim 1 has been amended. As amended, claim 1 particularly points out and distinctly claim the subject matter which Applicant regards as the invention, and obviates the indefinite grounds rejection of 35 U.S.C. §112, second paragraph.

Claims 2-20 depend directly or indirectly from amended claim 1 and are patentable for at least the reasons stated in support of claim 1.

**Claim Rejections 35 U.S.C. §102**

"A claim is anticipated only if each and every element as set forth in the claim is found . . . in a single prior art reference." Verdegaal Bros. v. Union Oil of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The elements must be shown to be present in the prior art reference either expressly or inherently. Rockwell International Corp. v. United States, 147 F.3d 1358, 1363 (Fed. Cir. 1998); Electro Med System S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

Not only must each and every element of a pending claim be shown in a single prior art reference, but the prior art reference must show each and every element in as complete detail as is contained in the pending claim. Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The disclosure "will not suffice as prior art if it was not enabling". In re Donohue, 226 USPQ2d 619, 621 (Fed. Cir. 1985), citing In re Borst, 45 USPQ 554, 557 (CCPA 1965), *cert. denied*, 148 USPQ 771 (1966). Further, the prior art reference must show each and every element arranged as required by the pending claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990).

**Rejection of Claims 1-4 Under 35 U.S.C. §102(b) is Improper**

Claims 1-4 have been rejected under 35 U.S.C. §102(b) as being anticipated by Psaros (U. S. Patent No. 5,765,558). The rejection of claims 1-4 is improper since Psaros fails to disclose, at least, a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane.

The device described in Psaros, for example as in Figure 1, is inserted through the patients' mouth and not following a tracheotomy. In addition, Psaros in Figure 5, for example, a membrane 46 is present which is made of a material intended to be permeable only to NO. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43.

Psaros also shows a device in Figure 7 which is to be inserted through a tracheal incision. This device has a does not contain window covered by an air-permeable membrane. The only membrane described in Psaros is membrane 46 that is made of a material intended to be permeable only to NO. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Since oxygen and carbon dioxide are major components of ambient air, it is clear Psaros does not disclose an air permeable membrane.

A tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane is simply not present in Psaros, and as such, a proper rejection under 35 U.S.C. §102 is improper for at least this reason.

Psaros not only does not disclose each and every element of the pending claims, but Psaros does not show each and every element arranged as required by the pending claims. For example, Psaros has no elements that can be properly asserted to be arranged as a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane. The Psaros device is clearly arranged either as a device without a membrane that is inserted through the patients mouth and not following a tracheotomy, or as device inserted through a tracheal incision. This device does not contain a window covered by an air-permeable membrane. For at least this additional reason, Psaros does not anticipate Applicants' claimed invention.

**Claims 1-4 are Additionally Non-Obvious Under a Proper 35 U.S.C. §103 Analysis**

The claimed invention is additionally non-obvious with regard to, at least, Psaros since there is at the minimum no suggestion or motivation present in the teaching or disclosure of Psaros, or in the references cited by the Examiner, to do what the Applicant has done in the claimed invention. For example, at a minimum Psaros does not teach or suggest a device having, at least, a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane. In fact, Psaros can be considered, at a minimum, to teach directly against arriving Applicant's claimed invention or produce a non-functional device. Applicant notes that as thoroughly discussed in a recent court holding:

"...the essential factual evidence on the issue of obviousness is set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors)." In re Lee, 61 USPQ2d, 1430 (Fed. Cir. 2002)

Such a rigorous examination required by law clearly would find the claimed invention non-obvious based on at least a study of the problem of allowing patient vocalization solved by the Applicant, and the functionality of the claimed invention. Psaros is directed toward permitting endogenous NO present in the patient's upper respiratory tract, and as such offers no motivation or suggestion to provide an air permeable membrane while allowing a patient to vocalize following a tracheotomy. Rather, for example, Psaros teaches away from the invention since the input port and membrane according to Psaros serves a different purpose. Therefore, one skilled in the art would not consider these elements while trying to provide for natural vocalization in-patients equipped with a tracheal cannula.

#### **Claim Rejections 35 U.S.C. §103**

To properly establish a *prima facie* case of obviousness three basic criteria must be met. First, there must some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. Second, there must be a

reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §2143.

Applicant respectfully notes that the combination of features found in the cited references in this case should be carefully examined. The courts have stated clearly that "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill. In re Hedges, 783 F.2d 1038, 228 USPQ 685, 687 (Fed. Cir. 1986), citing In re Wesslau, 353 F.2d at 241, 147 USPQ at 393.

**No Motivation or Suggestion for Proposed Modification and Combination Improper**

In order to properly make a *prima facie* case of obviousness, motivation or suggestion to combine or modify the references must be shown. The MPEP at §2143.01 states, "[I]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)"

**Rejection of Claims 5-6 Under 35 U.S.C. §103(a) Improper**

Claims 5-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros. Claims 5-6 depend either directly or indirectly on claim 1, and are patentable for at least the reasons that claim 1 is non-obvious. In addition, the rejection

of claims 5-6 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to make the asserted modification of a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane. For example, the membrane 46 described in Psaros is made of a material intended to be permeable only to NO. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Oxygen and carbon dioxide are major components of ambient air, and as such it is clear that Psaros does not teach or suggest an air permeable membrane. Since the proper motivation or suggestion is not present in Psaros a rejection under 35 U.S.C. §103(a) is improper.

**Rejection of Claims 7-12 Under 35 U.S.C. §103(a) Improper**

Claims 7-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros as applied to claims 1-6 above and further in view of of Muir (U.S. Patent No. 4,759,356). The rejection of claims 7-12 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to make the asserted modification of a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane.

For example, the membrane 46 described in Psaros is made of a material intended to be permeable only to NO, and Muir does not disclose a membrane. Psaros



states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Oxygen and carbon dioxide are major components of ambient air, and as such it is clear that Psaros does not teach or suggest an air permeable membrane. Since the proper motivation or suggestion is not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

In addition, the asserted combination of Psaros taken together with Muir would create a non-functional device. Muir discloses a valve designed for devices without cuffs. Adding such a valve to a device with a cuff, as disclosed in Psaros, would render the patient unable to breath out since the Muir valve closes upon exhalation and Psaros membrane is not air permeable.

Furthermore, a valve included in Psaros, as proposed by the Examiner, would in no way improve speech in the tracheotomized patient. In fact, the patient would be unable to vocalize at all since the Psaros device would extend through the mouth and past by the vocal cords.

**Rejection of Claims 13-18 and 20 Under 35 U.S.C. §103(a) Improper**

Claims 13-18 and 20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros as applied to claims 1-6 above and further in view of Abel (U.S. Patent No. 5,056,515). The rejection of claims 13-18 and 20 under 35 U.S.C. 103(a) is improper for, at least, the reason that there is no motivation or suggestion to make the asserted combination of a tracheal cannula having a shaft for insertion

following a tracheotomy into a trachea, wherein a shaft section extends above the cuff,  
the shaft section having a window covered by an air-permeable membrane.

For example, the membrane 46 described in Psaros is made of a material intended to be permeable only to NO, and Able does not disclose a membrane. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Oxygen and carbon dioxide are major components of ambient air, and as such it is clear that Psaros does not teach or suggest an air permeable membrane. Since the proper motivation or suggestion is not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

**Rejection of Claims 19 Under 35 U.S.C. §103(a) Improper**

Claims 19 been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros and Muir as applied to claim 7 above and further in view of Abel (U.S. Patent No. 5,056,515). As discussed above, the combination with regard to, at least, claim 7 is improper. As such, claim 19 is patentable for at least these reasons.

**All Claim Limitations Are Not Taught Or Suggested**

It is well established that when even one claimed limitation is not found in the combination of prior art, a rejection under 35 U.S.C. §103 is improper. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

**Rejection of Claims 5-6 Under 35 U.S.C. §103(a) Improper**

Claims 5-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros. The rejection of claims 5-6 under 35 U.S.C. 103(a) is improper for, at least, the reason that the asserted modification not contain a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane. The membrane 46 described in Psaros is made of a material intended to be permeable only to NO. Psaros states “permeability to oxygen and carbon dioxide in any case preferably should be poor”. Psaros at column 4, lines 42 and 43. Oxygen and carbon dioxide are major components of ambient air, and as such it is clear that Psaros does not teach or suggest an air permeable membrane. Since all the claimed elements are not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

In addition, Psaros teaches directly against a laced or woven PTFE as a material for a membrane. For example, at column 4, lines 42 and 43, Psaros states “permeability to oxygen and carbon dioxide in any case preferably should be poor”. Since it is well known in the art that a membrane comprising a fabric made of PTFE lacing would be air permeable is clear that Psaros does not teach or suggest all of the claimed elements. Since all the claimed element are not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

**Rejection of Claims 7-12 Under 35 U.S.C. §103(a) Improper**

Claims 7-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Psaros in view of Muir (US 4,759,356). The rejection of claims 7-12 under 35 U.S.C. 103(a) is improper for, at least, the reason that the asserted combination does not contain a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft section having a window covered by an air-permeable membrane. The membrane 46 described in Psaros is made of a material intended to be permeable only to NO. Psaros states “permeability to oxygen and carbon dioxide in any case preferably should be poor”. Psaros at column 4, lines 42 and 43. Oxygen and carbon dioxide are major components of ambient air, and as such it is clear that Psaros does not teach or suggest an air permeable membrane. Since all the claimed element are not present in Psaros a rejection under 35 U.S.C. §103(a) is improper.

In addition, Muir discloses a valve designed for devices without cuffs. Adding such a valve to a device with a cuff, as disclosed in Psaros, would render the patient unable to breath out since the Muir valve closes upon exhalation and Psaros membrane is not air permeable.

**Rejection of Claims 13-18 and 20 Under 35 U.S.C. §103(a) Improper**

The rejection of claims 13-18 and 20 under 35 U.S.C. 103(a) is improper for, at least, the reason that a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff, the shaft

section having a window covered by an air-permeable membrane is not present in the asserted combination.

For example, the membrane 46 described in Psaros is made of a material intended to be permeable only to NO, and Able does not disclose a membrane. Psaros states "permeability to oxygen and carbon dioxide in any case preferably should be poor". Psaros at column 4, lines 42 and 43. Oxygen and carbon dioxide are major components of ambient air, and as such it is clear that Psaros does not teach or suggest an air permeable membrane. Since the all of the claimed elements are not present in Psaros, a rejection under 35 U.S.C. §103(a) is improper.

#### **The References Teach Away From Each Other**

It is a well-established "general rule" that references that teach away cannot serve to create a *prima facie* case of obviousness. In re Gurley, 27 F3d 551, 553, 31 USPQ 2d 1131, 1132 (Fed Cir. 1994). A "reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Applicant." Winner v. Wang, 202 F.3d 1340 (Fed Cir. 2000) citing Gurley at 553.

The line of development flowing from the Psaros disclosure is unmistakably clear. Psaros is directed toward the use of endogenous NO for intubated patients. This is clear from, at least, Figure 1 where the input port 16 having the membrane 46 is shown in the orotracheal location. This positioning allows for NO present above the membrane to be carried from the upper respiratory tract (nose, paranasal sinus). The line of development

represented by Psaros is clearly unlikely to produce a tracheal cannula having a shaft for insertion following a tracheotomy into a trachea, wherein a shaft section extends above the cuff the shaft section having a window covered by an air-permeable membrane. For example, following a tracheotomy the device would be necessarily inserted into a trachea. As is well known in the art, secretory product would accumulate above the larynx and membrane. Psaros, recognizes this wherein in, for example, Figure 7 the tracheal tube is inserted through a tracheal incision and introduces gas flow through tube 64 and ejector device 63 (corresponding to the input port) into tracheotomy tube 62. See Psaros, column 5, lines 38 to 47. Tube and ejector device 63 are located outside the body of the patient so as to avoid any accumulation of secretory product inside the trachea. Since it is clear that the line of development flowing from Psaros would not result in the claimed invention, a rejection under 35 U.S.C. §103(a) can not be properly made.

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In summary, Applicant has addressed the pending objections and rejections. It is believed the application now stands in condition for allowance, and prompt favorable action thereon is earnestly solicited.

Respectfully submitted,

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